

Attorney's Docket No. 005493.P001

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application of:

Malcolm J. Simons

Application No.: 09/935,998

Filed: August 23, 2001

For: INTRON SEQUENCE ANALYSIS
METHOD FOR DETECTION OF
ADJACENT AND REMOTE LOCUS
ALLELES AS HAPLOTYPES

Examiner: Sisson, Bradley L.

Art Unit: 1634

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Enclosed is a copy of Information Disclosure Citation Form PTO-1449 or PTO/SB/08 together with copies of the documents cited on that form. It is respectfully requested that the cited documents be considered and that the enclosed copy of Information Disclosure Citation Form PTO-1449 or PTO/SB/08 be initialed by the Examiner to indicate such consideration and a copy thereof returned to applicant(s).

FIRST CLASS CERTIFICATE OF MAILING

I hereby certify that I am causing the above-referenced correspondence to be deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and that this paper or fee has been addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313

Date of Deposit: December 30, 2003

Name of Person Mailing Correspondence: Debbie Peloquin

Debbie Peloquin
Signature

12-30-03
Date

01/06/2004 SZEWDIE1 00000116 09935998

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Docket No.: 005493.P001
Application No.: 09/935,998

Pursuant to 37 C.F.R. § 1.97, the submission of this Information Disclosure Statement is not to be construed as a representation that a search has been made and is not to be construed as an admission that the information cited in this statement is material to patentability.

Pursuant to 37 C.F.R. § 1.97, this Information Disclosure Statement is being submitted under one of the following (as indicated by an "X" to the left of the appropriate paragraph):

_____ 37 C.F.R. §1.97(b).

X_____ 37 C.F.R. §1.97(c). If so, then enclosed with this Information Disclosure Statement is one of the following:

_____ A statement pursuant to 37 C.F.R. §1.97(e) or

X_____ A check for \$180.00 for the fee under 37 C.F.R. § 1.17(p).

_____ 37 C.F.R. §1.97(d). If so, then enclosed with this Information Disclosure Statement are the following:

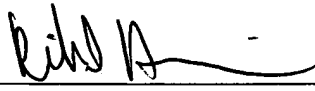
- (1) A statement pursuant to 37 C.F.R. §1.97(e); and
- (2) A check for \$180.00 for the fee under 37 C.F.R. §1.17(p) for submission of the Information Disclosure Statement.

If there are any additional charges, please charge Deposit Account No. 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: 12/30/02



Richard A. Nakashima
Reg. No. 42, 023

12400 Wilshire Blvd.
Seventh Floor
Los Angeles, CA 90025-1030
(303) 740-1980

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Substitut for Form 1449

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	09/935,998
Filing Date	08/23/2001
First Named Inventor:	Malcolm J. Simons
Art Unit	1634
Examiner Name	Sisson, Bradley L.
Attorney Docket Number	5493.P001

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NON PATENT LITERATURE DOCUMENTS

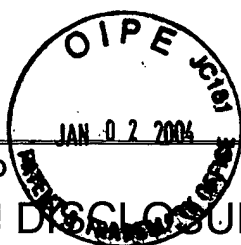
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		H.J. NOREEN ET AL. "VALIDATION OF DNA-BASED HLA-A AND HLA-B TESTING OF VOLUNTEERS FOR A BONE MARROW REGISTRY THROUGH PARALLEL TESTING WITH SEROLOGY", TISSUE ANTIGENS 57: 221-229, 2001.	
		C.K. HURLEY, ET AL. "LARGE-SCALE DNA-BASED TYPING OF HLA-A AND HLA-B AT LOW RESOLUTION IS HIGHLY ACCURATE SPECIFIC AND RELIABLE", TISSUE ANTIGENS 55: 352-358, 2000.	
		GENETIC TECHNOLOGIES LIMITED VS. APPLERA CORPORATION, "COMPLAINT FOR PATENT INFRINGEMENT" March 26, 2003.	
		GENETIC TECHNOLOGIES LIMITED VS. APPLERA CORPORATION, "FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT" August 12, 2003.	
		GENETIC TECHNOLOGIES LIMITED VS. APPLERA CORPORATION, "ANSWER AND COUNTERCLAIMS OF DEFENDANT APPLERA CORPORATION" September 5, 2003.	
		GENETIC TECHNOLOGIES LIMITED VS. APPLERA CORPORATION, "REPLY OF GENETIC TECHNOLOGIES LIMITED TO COUNTERCLAIMS OF APPLERA CORPORATION" September 25, 2003.	
		GENETIC TECHNOLOGIES LIMITED VS. APPLERA CORPORATION, "CORRECTED DISCLOSURES OF ASSERTED CLAIMS AND PRELIMINARY INFRINGEMENT CONTENTIONS" November 3, 2003.	
		GENETIC TECHNOLOGIES LIMITED VS. APPLERA CORPORATION, "APPLERA CORPORATION'S LOCAL RULE 3-3 PRELIMINARY INVALIDITY CONTENTIONS" December 1, 2003.	
		ERIC BOERWINKLE, WEIJUN XIONG, ERIC FOUREST, AND LAWRENCE CHAN, "RAPID TYPING OF TANDEMLY REPEATED HYPERVARIABLE LOCI BY THE POLYMERASE CHAIN REACTION: APPLICATION TO THE APOLIPOPROTEIN B 3' HYPERVARIABLE REGION, VOL. 86, PP. 212-216, JANUARY 1989	
		Little et al., "Nature", 285: 144-147, 1980	

Examiner Signature	Date Considered
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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SENT FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Substitute Form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	09/935,998
				Filing Date	08/23/2001
				First Named Inventor:	Malcolm J. Simons
				Art Unit	1634
				Examiner Name	Sisson, Bradley L.
Sheet	4	of	5	Attorney Docket Number	5493.P001
NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T ²
		GENETIC TECHNOLOGIES LIMITED VS. COVANCE, INC., AND VARIAGENICS, INC. NOW KNOWN AS NUVELO INC., "ANSWER AND COUNTERCLAIMS BY COVANCE, INC., AND NUVELO, INC., TO PLAINTIFFS COMPLAINT FOR PATENT INFRINGEMENT DEMAND FOR JURY TRIAL" August 26, 2003			
		ELSEVIER, "HUMAN IMMUNOLOGY", FOURTH ASIA-OCEANIA HISTOCOMPATIBILITY WORKSHOP, APRIL 22-29, 1993, PERTH, WESTERN AUSTRALIA, 1993HUMDQ 38(1), 1993, PP. 1, 2, 57-85.			
		MALCOLM D. MCGINNIS, ROGER V. LEBOWITZ, DAVID L. QUINN, AND MALCOLM J. SIMMONS, "ANCIENT, HIGHLY POLYMORPHIC HUMAN MAJOR HISTOCOMPATIBILITY COMPLEX DQA1 INTRON SEQUENCES, AMERICAN JOURNAL OF MEDICAL GENETICS, 52:438-444 (1994) © 1994 WILEY-LISS, INC.			
		M.J. NAUGHTON, T.M. LIMM, M.L. ASHDOWN AND M.J. SIMONS, "DPB1 LOCUS PCR-RFLP TYPING OF THE FOURTH ASIA-OCEANIA HISTOCOMPATIBILITY WORKSHOP CELL PANEL REVEALS A NOVEL DPB1 ALLELE, EUROPEAN JOURNAL OF IMMUNOGENETICS (1994), 21, 351-364			
		MARIAPIA A. DEGLI-ESPOSTI, ET AL., "CHARACTERIZATION OF 4A0HW CELL LINE PANEL INCLUDING NEW DATA FOR THE 10IHW PANEL, HUM. IMMUNOL. 1993, 38: 2-16.			
		MARIAPIA A. DEGLI-ESPOSTI, ET AL., "UPDATED CHARACTERIZATION OF THE FOURTH ANCESTRAL HAPLOTYPES USING ASIA-OCEANIA HISTOCOMPATIBILITY WORKSHOP PANEL", HUMAN IMMUNOLOGY 44, 12-18 (1995).			
		A.S.E.A.T.T.A. "DONOR REACTIVE ALLOANTIBODIES AUTO-ANTIBODIES REVISITED ASEATTA QUALITY CONTROL TRANSPLANTATION IN THAILAND", VOLUME 20, NUMBER 2, 1995, NEWSLETTER.			
		ASEATTA, 1996 ANNUAL SCIENTIFIC MEETING, M.J. SIMONS, GENETYPE P/L, FITZROY, VICTORIA, 3065.			
		M.D. VARNEY, A. GAVRILIDIS, B.D. TAIT, "POLYMORPHISM IN THE REGULATORY REGIONS OF HLA-DPB1" TISSUE TYPING LABORATORY, DEPARTMENT OF PATHOLOGY, THE ROYAL MELBOURNE HOSPITAL, GRATTAN STREET, PARKVILLE, 3050, AUSTRALIA.			
		Simons, M.J., et al. "HLA Haplotyping Using Non-Coding Polymorphisms", GeneType Pty. Ltd., P.O. Box 115, Fitzroy, Victoria 3065: Australia.			

Examiner Signature	Date Considered
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	09/935,998
Filing Date	08/23/2001
First Named Inventor:	Malcolm J. Simons
Art Unit	1634
Examiner Name	Sisson, B.
Attorney Docket Number	5493.P001

Sh et 2 of 5

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)				
		US-	4,582,788	04/15/1986	Erllich	
		US-	4,683,195	07/28/1987	Mullis et al.	
		US-	6,503,707	01/07/2003	Baxter-Lowe	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)					
		EPO-256 630 A1		24/02/1988	Howard Hughes Medical Institute		
		87305100.7					

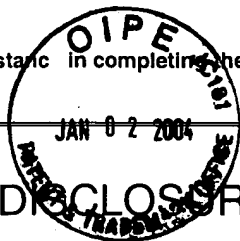
Examiner Signature		Date Considered	
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Sheet 3 of 5

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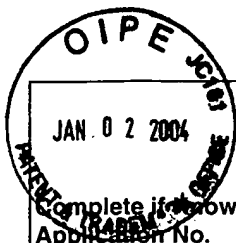
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		RUANO AND KIDD, "NUCL. ACID RES. 17: 8392, 1989	
		SALLER ET AL., AM. J. HUM. GENET., 45: A216, 1989	
		CORINNE WONG, CAROL E. DOWLING, RANDALL K. SAIKI, RUSSELL G. HIQUCHI, HENRY A. ERLICH, AND HAIG H. KAZAZIAN, "CHARACTERIZATION OF B-THALASSAEMIA MUTATIONS USING DIRECT GENOMIC SEQUENCING OF AMPLIFIED SINGLE COPY DNA", NATURE VOL. 330, NOVEMBER 26, 1989.	
		HUBERTUS J.M. SMEETS, HAN G. BRUNNER, HANS-HILGER ROPERS, AND BE WIERINGA, "USE OF VARIABLE SIMPLE SEQUENCE MOTIFS AS GENETIC MARKERS: APPLICATION TO STUDY OF MYOTONIC DYSTROPHY, HUM GENET (1989) 83: 245-251.	
		DIETHARD TAUTZ, "HYPERVARIABILITY OF SIMPLE SEQUENCES AS A GENERAL SOURCE FOR POLYMORPHIC DNA MARKERS", VOLUME 17, NUMBER 16, 1989.	
		NORMAN ARNHEIM, CAROLYN STRANGE, AND HENRY ERLICH, "USE OF POOLED DNA SAMPLES TO DETECT LINKAGE DISEQUILIBRIUM OF POLYMORPHIC RESTRICTION FRAGMENTS AND HUMAN DISEASE: STUDIES OF HLA CLASS II LOCI", VOL. 82. PP. 6970-6974, OCTOBER 1985	
		J. GEISEL, B. WEISSHAAR, K. OCTTE, AND W. DOERFLER, "A NEW APA LI RESTRICTION FRAGMENT LENGTH POLYMORPHISM IN THE LOW DENSITY LIPOPROTEIN RECEPTOR GENE 1), 2), J. CLIN. CHEM. CLIN. BIOCHEM, VOL. 26, 1988, PP. 429-433.	
		YUET WAI KAN AND ANDREE M. DOZY, "POLYMORPHISM OF DNA SEQUENCE ADJACENT TO HUMAN B-GLOBIN STRUCTURAL GENE: RELATIONSHIP TO SICKLE MUTATION", PROC. NATL. ASSOC. SCI. USA, VOL. 75, NO. 11, PP. 5631-5635, NOVEMBER 1978	
		SKOLNICK AND WALLACE, GENOMICS 2: 273-279, 1988.	
		GENETIC TECHNOLOGIES LIMITED VS. COVANCE, INC. AND VARIAGENICS, INC., NOW KNOWN AS NUVELO, INC., "COMPLAINT FOR PATENT INFRINGEMENT", MARCH 26, 2003.	

Examiner Signature	Date Considered
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**FEE TRANSMITTAL FOR FY 2004**

(FY 2004 Begins 10/01/2003)

TOTAL AMOUNT OF PAYMENT (\$) 180.00

Complete if known:

Application No. 09/935,998Filing Date August 23, 2001First Named Inventor Malcolm J. SimonsExaminer Name Sisson, Bradley J.Art Unit 1634Attorney Docket No. 05493.P001☐ Applicant claims small entity status. See 37 CFR 1.27.**METHOD OF PAYMENT** (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None☒ Deposit AccountDeposit Account Number : 02-2666

Deposit Account Name: _____

☒ The Director is Authorized to do the following with respect to the above-identified Deposit Account:☐ Charge fee(s) indicated below.☒ Credit any overpayments.☒ Charge any additional fees during the pendency of this application.☒ Any concurrent or future reply that requires a petition for extension of time should be treated as incorporating an appropriate petition for extension of time and all required fees should be charged.☐ Charge fee(s) indicated below except for the filing fee.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility application filing fee	_____
1002	340	2002	170	Design application filing fee	_____
1003	530	2003	265	Plant filing fee	_____
1004	770	2004	385	Reissue filing fee	_____
1005	160	2005	80	Provisional application filing fee	_____

SUBTOTAL (1) \$ _____

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims	Fee from below	Fee Paid
Total Claims	_____	- 20** =	_____	X _____	= _____
Independent Claims	_____	- 3** =	_____	X _____	= _____
Multiple Dependent	_____			_____	= _____

**Or number previously paid, if greater; For Reissues, see below.

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) \$ 180.00

FEE CALCULATION (continued)
3. ADDITIONAL FEES

<u>Larg Entity</u>		<u>Small Entity</u>		<u>Fee Description</u>	<u>Fee Paid</u>
<u>Fee Code</u>	<u>Fee (\$)</u>	<u>Fee Code</u>	<u>Fee (\$)</u>		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1813	8,800	1813	8,800	Request for inter parties reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	180.00
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	For filing a submission after final rejection (see 37 CFR 1.129(a))	
1814	110	2814	55	Statutory Disclaimer	
1810	770	2810	385	For each additional invention to be examined (see 37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	
1504	300	1504	300	Publication fee for early, voluntary, or normal pub.	
1505	300	1505	300	Publication fee for republication	
1803	130	1803	130	Request for voluntary publication or republication	
1808	130	1808	130	Processing fee under 37 CFR 1.17(i) (except provisionals)	
1454	1,330	1454	1,330	Acceptance of unintentionally delayed claim for priority	

Other fee (specify) _____

Other fee (specify) _____

SUBTOTAL (3) \$ 180.00

*Reduced by Basic Filing Fee Paid

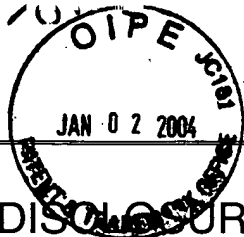
SUBMITTED BY:

Typed or Printed Name: Richard A. Nakashima

Signature:  Date: 12/30/03

R g. Number: 42,023 T e l e p h n Number: (303) 740-1980

Send to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450



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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		GAVRILIDIS, A., ET AL., "HLA DRB1 LOCUS SEQUENCE TYPING", GENETYPE, MELBOURNE, VICTORIA.	
		SHENG-JING LU, ET AL., "LINKAGE OF A NASOPHARYNGEAL CARCINOMA SUSCEPTIBILITY LOCUS TO THE HLA REGIONS", LETTERS TO NATURE, NATURE 346, 470-471 (1990);	

Examiner Signature	Date Considered
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